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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/291,656	03/03/1999	MARC PETERS-GOLDEN	UM-03662	2349

7590

07/15/2003

Medlin & Carroll LLP  
101 Howard Street Suite 350  
San Francisco, CA 94105

EXAMINER

CARLSON, KAREN C

ART UNIT

PAPER NUMBER

1653

20

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/291,656

Applicant(s)

PETERS-GOLDEN ET AL.

Examiner

Karen Cochran Carlson, Ph.D.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-25 and 27-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-25 and 27-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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This Office Action is in response to Paper #19, filed May 5, 2003. Claims 1-21 and 26 have been canceled. Claims 22-25 and 27-37 are currently pending and are under examination.

#### **Withdrawal of Objections and Rejections**

The objection to the disclosure because of the lack of a cross-reference to parent applications is withdrawn.

The rejection of Claims 22-25 and 27-37 under 35 U.S.C. 103(a) as being unpatentable over Gosselin et al. (USP 5,789,441; priority to February 15, 1996) as set forth in the previous Office Action is withdrawn.

#### **New Rejections**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 22-25 and 27-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Gosselin et al. (USP 5,789,441; priority to February 15, 1996).

Gosselin et al. teach leukotriene LTB<sub>4</sub> in a sterile liquid (cols. 11-13 and Example I, col. 14, lines 15-16, for example). The term "LTB<sub>4</sub>" includes leukotrienes C<sub>4</sub>, D<sub>4</sub>, and E<sub>4</sub> (col. 6, line 52).

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Therefore, Gosselin et al. teach a sterile liquid and a leukotriene (**Claim 22, 27, 28, 32, 33, 37**), wherein the leukotriene is LTB<sub>4</sub> (**Claim 23, 29, 34**), or wherein the leukotriene is a cysteinyl leukotriene (**Claim 24, 30, 35**) such as leukotrienes C<sub>4</sub>, D<sub>4</sub>, and E<sub>4</sub> (**Claim 25, 31, 36**).

While the claims recite that the solution is an aerosol or is in an endotracheal tube, a bronchoscope, or a nebulizer, for example, these phrases are given no patentable weight. See *Union Oil Co. of California v. Atlantic Richfield Co.*, 54 USPQ2d 1227, *In re Rosicky*, 125 USPQ 341; *In re Riden et al.*, 138 USPQ 112; *In re Lerner* 169 USPQ 51.

Claims 22, 23, 27-29, 32-34, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Imai et al. (1990; *Jpn J. Allergol* 39(10): 1380-1387, see English abstract attached to the reference).

Imai et al. teach leukotriene B<sub>4</sub> as an aerosol (**Claims 22, 23, 27**), said aerosol generated from the placement of LTB<sub>4</sub> into a nebulizer (**Claims 33, 34, 37**). The aerosolized LTB<sub>4</sub> was administered to anesthetized dogs. Anesthetized dogs are routinely ventilated and therefore the LTB<sub>4</sub> was administered through an endotracheal tube (**Claims 28, 29, 32**).

Claims 22, 23, 27-29, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin et al. (1989; *J. Clin. Invest.* 84: 1609-1619).

Martin et al. placed a flexible bronchoscope through the trachea of humans and wedged the bronchoscope into a subsegment of the lingual (page 1610, left col, para. 1). Leukotriene B<sub>4</sub> was instilled through the broncoscope into the subsegment. Therefore, Martin et al. teach a solution of LTB<sub>4</sub> (**Claim 22, 23, 27**), said solution undifferentiable from an aerosol solution because the droplets of solution are the same as the liquid. The LTB<sub>4</sub> was placed into a

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bronchoscope, which was passed through the trachea and is therefore also an endotracheal tube (**Claim 28, 29, 32**).

Claims 22, 23, 27-29, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson et al. (1991; Agents and Actions 33(3/4): 260-271).

Johnson et al. placed leukotriene B4 into an endotracheal tube (page 261, right col.; **Claim 28, 29, 32**). This solution is undifferentiable from an aerosol solution because the droplets of solution are the same as the liquid (**Claim 22, 23, 27**).

Claims 22, 24, 25, 27, 28, 30-33, and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujimura et al. (1991; Prostaglandins 42(4): 379-389).

Fujimura et al. teach leukotriene C4 as an aerosol (**Claim 22, 24, 25, 27**), said aerosol generated from the placement of the LTC4 into a nebulizer (page 380, para. 3; **Claim 33, 35-37**). The guinea pigs were ventilated via tracheal cannulation with a polyethylene tube; therefore, the LTC4 solution was placed into an endotracheal tube (**Claim 28, 30-32**).

Claims 22, 24, 25, 27, 28, 30-33, and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Ludwig et al. (1988; J. Appl. Physiol. 65(3): 1424-1429).

Ludwig et al. teach leukotriene C4 as an aerosol (**Claim 22, 24, 25, 27**), said aerosol generated from the placement of the LTC4 into a nebulizer (page 1425, right col, para. 2; **Claim 33, 35-37**). The aerosolized LTC4 was administered through a bronchoscope (**Claim 28, 30-32**).

Claims 22, 24, 25, 27, 33, and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Ball et al. (1991; J. Pharmacol. Methods 26: 187-202).

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Ball et al. teach leukotriene D4 as an aerosol (**Claim 22, 24, 25, 27**), said aerosol generated from the placement of the LTD4 into a nebulizer (page 197; **Claim 33, 35-37**).

Claims 22, 24, 25, 27, 28, 30-33, and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson et al. (1985; Prostaglandins 29(2): 313-322)

Johnson et al. teach leukotriene D4 as an aerosol (**Claim 22, 24, 25, 27**), said aerosol generated from the placement of the LTD4 into a nebulizer (**Claim 33, 35-37**) and administered through an endotracheal tube (page 315, para. 2; **Claims 28, 30-32**).

Claims 22, 24, 25, 27, 28, 30-33, and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Donnell et al. (1984; Agents and Actions 14(1): 43-48).

O'Donnell et al. teach leukotriene D4 and leukotriene E4 as an aerosol (**Claim 22, 24, 25, 27**), said aerosol generated from the placement of the LTD4 or LTE4 into a nebulizer (page 44, left col; **Claim 33, 35-37**). The aerosolized LTD4 or LTE4 was administered through an endotracheal tube (**Claim 28, 30-32**).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-25 and 27-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gosselin et al. (USP 5,789,441; priority to February 15, 1996) in view of Fujimura et al. (1991; Prostaglandins 42(4): 379-389).

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Gosselin et al. teach leukotriene LTB<sub>4</sub> in a sterile liquid (cols. 11-13 and Example I, col. 14, lines 15-16, for example). The term "LTB<sub>4</sub>" includes leukotrienes C<sub>4</sub>, D<sub>4</sub>, and E<sub>4</sub> (col. 6, line 52). In Example 5, Gosselin et al. teach that LTB<sub>4</sub> is an antiviral agent. At col. 11, line 32, Gosselin et al. set forth suitable modes of administration of pharmaceutical compositions of LTB<sub>4</sub> include in an aerosol solution.

It is routine in the art to make aerosol solutions for the administration of agents to the lungs. Fujimura et al. teach leukotriene C<sub>4</sub> as an aerosol, said aerosol generated from the placement of the LTC<sub>4</sub> into a nebulizer (page 380, para. 3). The guinea pigs were ventilated via tracheal cannulation with a polyethylene tube; therefore, the LTC<sub>4</sub> solution was placed into an endotracheal tube.

Therefore, it would have been obvious to a person having ordinary skill in the art to place the sterile liquid and a leukotriene (**Claims 26, 27, 28, 32, 37**), wherein the leukotriene is LTB<sub>4</sub> (**Claims 23, 29, 34**), or wherein the leukotriene is a cysteinyl leukotriene (**Claim 24, 30, 35**) such as leukotrienes C<sub>4</sub>, D<sub>4</sub>, and E<sub>4</sub> (**Claims 25, 31, 36**) as taught by Gosselin et al. into a nebulizer (**Claim 33**) to make an aerosol solution of LTB<sub>4</sub> as defined by Gosselin et al. (**Claim 22**) and administer the aerosol to the lungs via an endotracheal tube (**Claim 28**) for the treatment of viral infections because Gosselin et al. teach that LTB<sub>4</sub> is an antiviral agent and suggest that LTB<sub>4</sub> can be administered as an aerosol and Fujimura et al. teach that leukotriene solutions can be placed into a nebulizer for aerosolization and administered to the lungs via an endotracheal tube. Thus, the placement of leukotrienes into a nebulizer for aerosolization and administration to lungs via an endotracheal tube is predictable because Fujimura et al. expressly demonstrate this method of administering leukotrienes.

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Claims 22-25 and 27-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gosselin et al. (USP 5,789,441; priority to February 15, 1996) in view of Ludwig et al. (1988; J. Appl. Physiol. 65(3): 1424-1429).

Gosselin et al. teach leukotriene LTB<sub>4</sub> in a sterile liquid (cols. 11-13 and Example I, col. 14, lines 15-16, for example). The term "LTB<sub>4</sub>" includes leukotrienes C<sub>4</sub>, D<sub>4</sub>, and E<sub>4</sub> (col. 6, line 52). In Example 5, Gosselin et al. teach that LTB<sub>4</sub> is an antiviral agent. At col. 11, line 32, Gosselin et al. set forth suitable modes of administration of pharmaceutical compositions of LTB<sub>4</sub> include in an aerosol solution.

It is routine in the art to make aerosol solutions for the administration of agents to the lungs. Ludwig et al. teach leukotriene C<sub>4</sub> as an aerosol, said aerosol generated from the placement of the LTC<sub>4</sub> into a nebulizer (page 1425, right col, para. 2). The aerosolized LTC<sub>4</sub> was administered through a bronchoscope.

Therefore, it would have been obvious to a person having ordinary skill in the art to place the sterile liquid and a leukotriene (**Claims 26, 27, 28, 32, 37**), wherein the leukotriene is LTB<sub>4</sub> (**Claims 23, 29, 34**), or wherein the leukotriene is a cysteinyl leukotriene (**Claim 24, 30, 35**) such as leukotrienes C<sub>4</sub>, D<sub>4</sub>, and E<sub>4</sub> (**Claims 25, 31, 36**) as taught by Gosselin et al. into a nebulizer (**Claim 33**) to make an aerosol solution of LTB<sub>4</sub> as defined by Gosselin et al. (**Claim 22**) and administer the aerosol to the lungs via an bronchoscope (**Claim 28**) for the treatment of viral infections because Gosselin et al. teach that LTB<sub>4</sub> is an antiviral agent and suggest that LTB<sub>4</sub> can be administered as an aerosol and Ludwig et al. teach that leukotriene solutions can be placed into a nebulizer for aerosolization and administered to the lungs via a bronchoscope. Thus, the placement of leukotrienes into a nebulizer for aerosolization and administration to lungs via an bronchoscope is predictable because Ludwig et al. expressly demonstrate this method of administering leukotrienes.

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It is noted that the claims were amended with the submission of the RCE to add "antibiotic" to the claims, and have now been re-amended to delete the inclusion of an antibiotic. Thus, many of these same rejections were made in the final rejection, Paper #12, mailed May 7, 2002.

### Response to Arguments

Applicant's Argument A urges that the Examiner has not considered all of the claim elements and that the cited case law does not target the present claim language. The claims have been amended and as now claimed the rejections have been substantially changed. However, Applicants have not pointed out how the a solution of leukotrienes that is aerosolized or in a nebulizer, endotracheal tube or bronchoscope is different from that in a test tube? Therefore, Gosselin et al. now anticipate the claims or render the claims obvious for reasons different from those set forth in the previous Office Action, due to the amendments to the claims.

Argument B at page 7 is no longer germane to the rejections of record.

Argument C at page 7 is no longer germane to the rejections of record.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the

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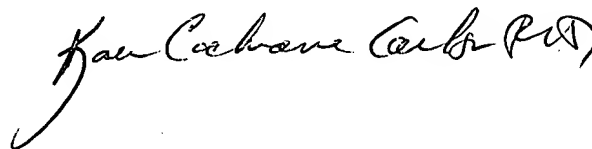
date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:30 AM - 5:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

July 9, 2003



KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER